Remarks

This is in response to the Office Action mailed November 28, 2007 in the subject application.

Applicant respectfully requests this response be entered as a REQUEST FOR CONTINUED EXAMINATION.

Claims 97-123 were pending at the time of the mailing of the instant Office Action. The subject application contains (3) three independent claims, claims 97, 101, and 119, each of which are amended herein. Support for the amendments is indicated by referencing, in brackets, paragraph numbers in the published application (U.S. Patent Application 2002/0042726).

Applicant hereby requests allowance based on the claim amendments and representations submitted herein.

Statement of Substance of Interview

Applicant gratefully acknowledges the courtesy of a telephone interview with Examiner Porter and Supervising Examiner Thomas on February 13, 2008, with Applicant's attorneys David Barman and Robert Schwartz. The Examiners have kindly suggested inclusion of claim language relating to the steps having association of a patient identifier with a particular formulary. Applicant has amended the claims herein in accordance with the suggestions.

Claim Rejections - 35 USC § 102

Claims 119 and 120 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Renvall (WO 91/024447).

The current Office Action purports that Renvall discloses the claimed method for aggregating electronic prescription data.

The Office Action cites Figure 2, and page 5, lines 22-27 of the Renvall reference. However, as will be explained, the citation does not provide for any electronic "identifying" or "associating" as provided for in the claimed invention.

The Office Action also incorrectly states that the manner of forming the drug list pertinent. This is an incorrect characterization. The method of the present invention, as claimed, requires "using the patient identifier, electronically identifying from the database of drugs, a formulary list of drugs approved by a drugs benefit provider."

The specification of the present invention states:

> By means of the system, drug formulary guidelines effectively adapt to the user's prescribing patterns or can be followed effortlessly by the prescriber. This desirable prescriber-centricity can be obtained by giving priority to the prescriber's personal or custom lists or, better still if they are a subset of these, to the patient's history lists, and system-identifying

> patient-formulary preferences on those lists for easy final picking by the prescriber. Where the prescriber is selecting a drug providing effective therapy for a just-specified condition, the above procedure may often clearly identify a single drug meeting all requirements or may result in a short list of a very small number of drugs for final selection. Where no drug is listed as meeting all requirements, the system may so alert the user and suggest formulary drugs not on the doctor-specific lists or ask the user whether they wish to review appropriate non-formulary drugs from their personal or custom lists.

(Published Application, at paragraph 0278)

> Typically, drug formularies comprise lists of preferred drugs whose costs will be borne by a drugs benefit house.

(Published Application, at paragraph 0007)

Formulary, refers to a list of drugs. The list may be a list of physician preferred drugs, or a list of preferred dugs provided by a drugs benefit provider.

In the claimed invention, the patient identifier electronically associates a patient with a specific formulary preferred drug for that patient's drug benefit provider. According to the present invention, when a prescriber inputs the patient identifier, a specific list of formulary approved drugs based on the patient's drugs benefit provider is then accessed. Thus, the "using the patient identifier, electronically identifying from the database of drugs, a formulary list of drugs approved by a drugs benefit provider" and "electronically associating

with the patient identifier, a drug selected from the formulary list of drugs approved by a drugs benefit provider" are steps in the method of the claimed invention. There is no need, as purported in the Office Action, to have a step requiring "approving drugs." The drugs have already been approved and are in the list of preferred (e.g., approved) drugs provided by the drug benefit provider. Although, various therapies may exist for a given condition, the drug benefits provider typically has preferred pricing for specific therapies. As stated in para. [0278] of the specification of the subject application (as published) "the system may so alert the user and suggest formulary drugs."

These electronic "identifying" and "associating" steps are not taught in the Renvall reference.

The claimed "prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the first patient," and "one prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the second patient," is not taught or suggested anywhere in the barcode system disclosed in Renvall.

Renvall teaches an electronic barcode reader wherein the user scans a barcode associated with a particular patient and then selects a barcode (corresponding to a therapy) to be scanned for a specific therapy to be used for that patient. Renvall discloses a user manually selecting a bar code to be scanned from a plurality of bar codes available in a bar code catalog

(Renvall page 6, lines 26-30 and page 7, line 33). The user selects a catalog page and scans a bar code into a reader.

In summary, Renvall allows a prescriber to manually select therapy from a list in a bar code catalog. There is nothing in the teaching of Renvall that directs the prescriber to a preferred therapy for a patient based on the patients drugs benefit provider formulary preference.

A rejection under 35 USC § 102(b) requires each and every element of the claim to be taught. Renvall is deficient in that it does not teach "prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the first patient," and "one prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the second patient," or "aggregating data from the at least a first patient record with data from the at least a second data patient record to form an aggregated data record; and outputting the aggregated data record" as now claimed in claim 119.

Because Renvall fails to teach each and every element of claims 119 and 120, a rejection under 35 U.S.C. § 102(b) cannot be properly applied and cannot be the basis for a rejection under 35 USC 102(b). Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim Rejections - 35 USC § 103

Claims 121-122 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall.

Claims 121-122 are dependent on claim 119.

As stated above, Renvall does not teach or suggest the method set forth in pending claim 119. Renvall is deficient because Renvall teaches manual selection of a bar code that is paired with a particular drug. Renvall has no disclosure for identifying formulary preferred drugs as claimed.

The subject application teaches, in para. [0220]

> A further valuable feature of the novel prescription management system described herein is an ability to review a completed prescription for contraindications, or relative contraindications, such as patient allergies to the prescribed drug and such as possible drug-to-drug interactions with other drugs the patient has previously been prescribed.

There is no teaching, suggestion, or motivation to modify the manual bar code selection teaching of Renvall to arrive at "prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the first patient," and "one prescribed drug selected from a formulary list of drugs approved by a drugs benefit provider for the second patient," or

"aggregating data from the at least a first patient record with data from the at least a second data patient record to form an aggregated data record; and outputting the aggregated data record" as now claimed in claim 119.

Further, the rejections under 35 USC 103(a) over Renvall alone, and the rejection of claim 123 over Renvall in view Official Notice still fails to render the subject invention obvious.

The method of claim 123 is not merely the sale of "lead data" as characterized by the Office Action, page 5. Privacy concerns and HIPPA requirements led to the development of the present method which compiles and aggregate record of multiple patients identifiable by an "identifier" and not by patient name. The patient identifier is disclosed in the specification as filed to be a mechanism by which privacy and security are maintained. See application as published paragraphs [0136]-[0141] and [0143]. There is no teaching or suggestion either in Renvall alone, or in combination with the "Big Brother" reference provided to substantiate Official Notice, has a teaching or suggestion for the invention as claimed in claim 123.

Without a proper teaching, suggestion, or motivation to modify, a rejection under 35 U.S.C. § 103(a) cannot be properly applied. Applicant respectfully requests reconsideration and withdrawal of these rejections.

Claims 97-106 and 114-118 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of Brown, "A Computerized Prescription Program for Doctors (hereinafter "Brown"), and Doyle, U.S. Patent No. 5,070,452 (hereinafter '452 patent).

Claims 97 and 101 are independent claims.

Each of claims 97 and 101 now requires:

> electronically associating the patient identifier with a drug benefits provider or insurance company for a patient associated with the patient identifier;
>
> electronically accessing a formulary associated with the drug benefits provider or insurance company for a patient associated with the patient identifier;
>
> electronically identifying from the database of drugs, a list of formulary drugs approved by a drugs benefit provider for the patient associated with patient identifier;
>
> electronically associating with the patient identifier, a formulary drug selected from the list of formulary drugs approved by a drugs benefit provider;

Renvall, as discussed above, is a simple bar code selection/reader and does not have any disclosure for a patient identifier, as discussed in relation to claim 123 (above), and association of the identifier with a drug benefits provider, electronically accessing a formulary associated with the drug benefits provider or insurance company for a patient associated

with the patient identifier; electronically identifying from the database of drugs, a list of formulary drugs approved by a drugs benefit provider for the patient associated with patient identifier; electronically associating with the patient identifier, a formulary drug selected from the list of formulary drugs approved by a drugs benefit provider; as required in the pending claims. The Office Action purports, the Brown reference teaches the formulary requirement of the pending claims. Brown teaches a "doctor's personal drug formulary" (page 101). This is the list of drugs preferred by the **doctor**, not the formulary of a **drug benefits provider** as required in the claims.

The Office Action then combines the teachings of Renvall and Brown with the '452 patent. However, the '452 patent only discloses authorization for covered medical treatments. The '452 patent does not teach or suggest formulary approved drugs, as claimed in the subject application. A particular patient may be authorized to receive hypertension medication under the system of the '452 patent, but the '452 patent has no teaching or suggestion for a formulary preferred drug to be prescribed from the many hypertension drugs available.

Applicant asserts independent claims 97 and 101 are patentable over these cited reference, each of the claims dependent thereon are also patentable.

Absent any teaching, suggestion, or motivation to modify a rejection under 35 U.S.C. § 103(a) cannot be properly applied.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim 107 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of Brown and Doyle as applied to claim 101 and further in view of Howson, U.S. Patent 5,088,981 (hereinafter, the '981 patent). Claim 107 depends ultimately on independent Claim 101 with the addition of "electronically associating with the patient identifier allergy or drug interaction information regarding the patient or patient drug formulary changes." The patient identifier limitation is discussed above in relation to claim 123. The '981 patent discloses interaction information but does not have any recitation of the word "allergy." Additionally, the method of claim 107 provides an alert when the formulary changes and the drugs on the changed formulary have an interaction or allergy concern for the patient associated with the patient identifier. There is no teaching or suggestion in the '981 patent alone or in any combination with Renvall, Brown and the '452 patent, to perform an interaction or allergy alert based on the changes in a drug formulary.

Without a proper teaching, suggestion, or motivation to modify, a rejection under 35 U.S.C. § 103(a) cannot be properly applied. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 108-112 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall in view of Brown and Doyle as applied to claims 101 and 103 and further in view of "Data Hard to Get" (hereinafter "DATA").

Claims 108-112 depend ultimately on claim 101. As stated above, claim 101 is patentable over the cited references. Combination with DATA, in view of the cited references, does not cure the deficient teaching of the cited references. The Office Action alleges the DATA reference teaches "patient data and drug formulary data." This is incorrect. DATA has no recitation of the word "formulary." DATA is a reference discussing the monitoring of billed charges and benefits paid for prescription drugs. Thus, because DATA does not disclose, or in anyway teach or suggest the formulary limitations of the claims 101, 103, and 108-112, DATA cannot be used to render the claimed invention obvious. Because DATA is also deficient, and does not cure the deficiencies discussed above in the cited references, combination of DATA in view of Renvall, Brown, and the '452 patent fails to render the claimed invention obvious. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim 113 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Renvall, Brown and Doyle and further in view of the (Howson) '981 patent. Claim 113 depends on claim 101. As discussed above, claim 101 is not obvious in view of the cited Renvall, Brown and Doyle ('452 patent) references. Claim 113 requires "the step of logging information as to the time,

date and identity of third party access to the prescription, to provide a user data access audit trail." However, applicant asserts the '981 patent does not teach prescription access. The '981 patent (col. 16, lines 6-46, as cited on page 16 of the Office Action), only discloses a time/date stamp relating to changes in a treatment protocol. This is not the time, date, and identity of those accessing prescription information, as currently claimed. Using the teaching of the '981 patent, if one were to view a prescription, and not make any changes, no record is created. The record created in the '981 only occurs if changes are made. Thus, the cited Renvall, Brown and Doyle ('452 patent) and further in view of the (Howson) '981 patent are deficient and still do not provide any teaching or suggestion to render the subject application obvious.

Without a proper teaching, suggestion, or motivation to modify, a rejection under 35 U.S.C. § 103(a) cannot be properly applied. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Based on the Amendments presented herein, Applicant respectfully asserts the application is now in condition for allowance. If the Examiner believes there are any additional issues that have not been resolved, the Examiner is invited to call the undersigned representative who is attorney of record in this case.

The Commissioner is hereby authorized to charge our Deposit Account No. 190734, should additional fee(s) be required, or credit any overpayment, in the filing of this document to expedite the prosecution of this application.

Respectfully submitted,

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